

## REMARKS

The amendments set out above and the following remarks are believed responsive to the points raised by the Office Action dated October 30, 2001. In view of the amendments set out above and the following remarks, reconsideration is respectfully requested.

### The Pending Claims

As a convenience for the Examiner, a complete set of the pending claims is attached to this response as an Appendix.

Claim 1 has been amended. Claims 1-9, 13-42, and 66-67 are pending.

The amendment to claim 1 is supported, for example, at specification page 11, lines 4-10. This amendment does not constitute the addition of new matter.

Several changes have been made in the specification to improve its form. These changes do not constitute the addition of new matter.

### The Office Action

The Office Action set forth the following grounds for rejection: (1) claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; (2) claims 1-9 and 13-34 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent No. 4,361,483 ("Pall '483") in view of U.S. Patent No. 5,846,421 ("Ohtani") or U.S. Patent No. 4,926,354 ("Meyering et al."); (3) claims 35-40 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Pall '483 in view of Ohtani or Meyering et al. as applied to claim 30 above and further in view of U.S. Patent No. 1,264,718 ("Wagner"); and (4) claims 41 and 42 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Pall '483 in view of Ohtani or Meyering et al. in view of Wagner as applied to claim 39 above and further in view of U.S. Patent No. 1,579,567 ("Schriner").

### Discussion of 35 U.S.C. § 112, Paragraph Two Rejection

Claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner objected to the use of "FLUORODYNE" and "SUPOR" in claim 6 as being unclear. The Applicants disagree with the Examiner.

The Applicants submit that the specification identifies FLUORODYNE and SUPOR as suitable filter media available from Pall Corporation as set forth at specification page 10, lines 16-18. Further, the Applicants submit that names used in trade are permissible in patent

applications, and, in particular, the meanings of FLUORODYNE and SUPOR were well-known and satisfactorily defined in the literature at the time the present application was filed. (See MPEP § 608.01(v)). For example, both FLUORODYNE and SUPOR were registered Trademarks by Pall Corporation or Pall Corporation's subsidiary Gelman Sciences, Inc. at the time the application was filed. The Applicants submit that the compositions of the FLUORODYNE filter medium and the SUPOR filter medium correspond to the compositions of the water-wettable filter medium available from Pall Corporation under these trade designations.

In particular, FLUORODYNE was registered as a Trademark on March 14, 1989. Furthermore, the meaning of FLUORODYNE filter medium was well established in the literature, for example, in patents and in commercial literature available from Pall Corporation. For example, see the attached commercial literature and issued patent available at the time the application was filed including "Filter Reference Guide: A Summary Of Available Disposable Pall Filter Media and Cartridge Styles," copyrighted 1989; "Selection Guide Fluorodyne® Filters (P Grade)," copyrighted 1989; "Selection Guide Fluorodyne™ Filters (E Grade) For DI Water and Chemicals," copyrighted 1989; and U.S. Patent No. 5,415,781 to Randhahn et al. issued on May 16, 1995. These references are submitted with this response in the attached Information Disclosure Statement.

In particular, SUPOR was registered as a Trademark on June 27, 1989. Furthermore, the meaning of SUPOR filter medium was well established in the literature, for example, in patents, commercial literature available from Pall Corporation and Pall Corporation's subsidiary Gelman Sciences, and various published articles. For example, see the attached references available at the time the application was filed including "New Products," The Scientist, November 25, 1996; "New Products," The Scientist, March 21, 1994; "Development of Chitosan-Based Ultrafiltration Membranes for Protein Separation," available at [http://www.che.utexas.edu/nams/NAMS97\\_Abs/Posters/P21.html](http://www.che.utexas.edu/nams/NAMS97_Abs/Posters/P21.html), last modified February 15, 1998; and U.S. Patent No. 5,490,938 to Sawan et al. issued on February 13, 1996. These references are submitted with this response in the attached Information Disclosure Statement.

Thus, it is respectfully submitted that the basis for rejection under 35 U.S.C. §112, second paragraph, has now been overcome and should be withdrawn.

Discussion of Obviousness Rejection over Pall '483 in view of Ohtani or Meyering et al.

Claims 1-9 and 13-34 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Pall '483 in view of Ohtani or Meyering et al. This rejection is respectfully traversed.

Claim 1 defines a filter assembly comprising a filter medium having first and second ends, the first end of the filter medium being embedded in a first end cap at a first

joint and the second end of the filter medium being embedded in a second end cap at a second joint, wherein the characteristics of the filter medium at the joints are not materially changed. Thus, claim 1 defines a filter assembly in which the material of the end cap may or may not fill the pores of the filter medium when the filter medium is embedded in the end cap, but the characteristics of the filter medium are not materially changed prior to being embedded. The resulting filter assembly as claimed has several advantages over conventional filter assemblies. One advantage of the filter assembly of claim 1 is that no additional material other than the material of the end cap or the material of the filter medium is introduced. Thus, there are fewer sources for contamination to the assembly. Another advantage of the filter assembly is that the filter medium is not altered physically, e.g., there is no physical destruction of the filter medium, so there is no damage done to the membrane.

Nothing in the references cited by the Examiner, nor in their combination, discloses or suggests a filter assembly comprising a filter medium having first and second ends, the first end of the filter medium being embedded in a first end cap at a first joint and the second end of the filter medium being embedded in a second end cap at a second joint, wherein the characteristics of the filter medium at the joints are not materially changed.

Upon reading the principle reference, Pall '483, one of ordinary skill in the art would not be taught to embed the filter medium in end caps to form joints. Pall '483 does not disclose or suggest embedding a filter medium into end caps. Pall '483 discloses a disposable pharmaceutical filter assembly. The filter assembly includes a filter element 3 including a tubular filter 8 confined between end caps 9,10, each sealed to the ends of the filter tube 8 by a potting compound 11. (See Pall '483, column 4, lines 32-34).

Ohtani discloses a microfiltration membrane cartridge having a microfiltration membrane 13 which is filled with high molecular-weight polymers at the end portions prior to fusing them to end plates 17. (See Ohtani, column 3, lines 32-41 and Figure 2). The membrane of Ohtani is disclosed and taught to be materially changed prior to being fused with the end plates.

Meyering et al. discloses making the ends 16 of filter membrane 12 substantially non-porous and then embedding the ends into end caps. (See Meyering et al., column 8, lines 30-32 and 54-61). For example, Meyering et al. teaches using crushing rollers 48 along the longitudinal borders of the filtration area, collapsing the pores of the membrane to produce the nonporous area. (See Meyering et al., column 12, lines 44-48). Further, Meyering et al. also discloses making the ends nonporous by casting the ends in a polymer and thus filling the pores of the ends prior to being inserted into the end caps.

(See Meyering et al., column 13, lines 14-28). Even further, Meyering et al. teaches that the ends of the membrane may be heat sealed with a nonporous tape. (See Meyering et al., column 14, lines 1-16). Therefore, the membrane of Meyering et al. is disclosed and taught to be materially changed prior to being embedded into the end caps.

Nothing in Pall '483, Ohtani, or Meyering et al. discloses a filter assembly comprising a filter medium having first and second ends, the first end of the filter medium being embedded in a first end cap at a first joint and the second end of the filter medium being embedded in a second end cap at a second joint, wherein the characteristics of the filter medium at the joints are not materially changed, as claimed in claim 1. Further, no combination of these references make claim 1 obvious. One of ordinary skill in the art reading Pall '483 in view of Ohtani or Meyering et al. would never make a filter assembly comprising a filter medium having first and second ends embedded in first and second end caps, wherein the characteristics of the filter medium at the joints are not materially changed prior to embedding, because each of these references disclose and teach materially changing the membrane prior to joining it with the end cap.

Therefore, claim 1 and dependent claims 2-9 and 13-34 are nonobvious over Pall '483 in view of Ohtani or Meyering et al.

Discussion of Obviousness Rejection over Pall ' 483 in view of Ohtani or Meyering et al. as applied to claim 30 and further in view of Wagner

Dependent claims 35-40 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Pall '483 in view of Ohtani or Meyering et al. as applied to claim 30 above and further in view of Wagner. This rejection is respectfully traversed.

With respect to the rejection over Pall '483 in view of Ohtani or Meyering et al., the Applicants submit that in view of the arguments set out above, the rejected claims are nonobvious in view of these references.

With respect to Wagner, Wagner discloses a faucet spout which may be readily repaired. (See Wagner, column 1, line 11). Nothing in Wagner discloses or suggests a filter assembly comprising a filter medium having first and second ends, the first end of the filter medium being embedded in a first end cap at a first joint and the second end of the filter medium being embedded in a second end cap at a second joint, wherein the characteristics of the filter medium at the joints are not materially changed, as claimed in claim 1. Accordingly, Wagner, even when combined with the other references, fails to render claim 1 or dependent claims 35-40 unpatentable.

Discussion of Obviousness Rejection over Pall ' 483 in view of Ohtani or Meyering et al. in view of Wagner as applied to claim 39 and further in view of Schrinier

Dependent claims 41 and 42 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Pall '483 in view of Ohtani or Meyering et al. in view of Wagner as applied to claim 39 above and further in view of Schrinier. This rejection is respectfully traversed.

With respect to the rejection over Pall '483 in view of Ohtani or Meyering et al. in view of Wagner, the Applicants submit that in view of the arguments set out above, the rejected claims are nonobvious in view of these references.

With respect to Schrinier, Schrinier discloses a faucet which may be quickly operated to give a full flow and closed completely to entirely shut off the flow. (See Schrinier, column 1, lines 12-17). Nothing in Schrinier discloses or suggests a filter assembly comprising a filter medium having first and second ends, the first end of the filter medium being embedded in a first end cap at a first joint and the second end of the filter medium being embedded in a second end cap at a second joint, wherein the characteristics of the filter medium at the joints are not materially changed, as claimed in claim 1. Accordingly, Schrinier, even when combined with the other references, fails to render claim 1 or dependent claims 41 and 42 unpatentable.

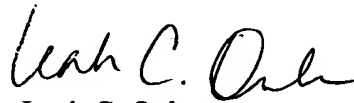
In re Appln. of Gutman et al.  
Application No. 09/462,765

Conclusion

The application is considered in good and proper form for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

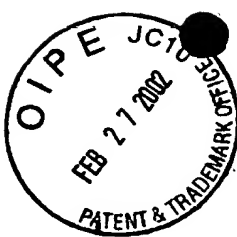
Respectfully submitted,

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PATENT  
Attorney Docket No. 440191/PALL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GUTMAN et al.

Application No. 09/462,765

Art Unit: 1723

Examiner: M. Savage

Filed: June 2, 2000

For: FILTER ASSEMBLY

AMENDMENTS TO SPECIFICATION, CLAIMS, AND ABSTRACT  
MADE IN RESPONSE TO OFFICE ACTION DATED OCTOBER 30, 2001

*Amendments to the paragraph beginning at page 5, line 7:*

p.m. According to ~~a first~~ an aspect of the invention, there is provided a filter assembly comprising a plastics housing providing an inlet port and an outlet port, the material of the housing being such that the assembly can be sterilized by subjecting the interior of the housing to steam under pressure while the exterior of the housing is at atmospheric pressure without damaging the housing, a filter element held in the housing and comprising a filter medium of water wettable material having a central passage extending between first and second ends of the filter medium, the first end of the filter medium being embedded in a first end cap of a plastics material at a first joint to close said passage and the second end of the filter medium being embedded in a second end cap of a plastics material at a second joint, wherein the characteristics of the filter medium at the joints are not materially changed, said second end cap providing a fluid connection between said passage and one of said ports, the first and second end caps forming respective water-wettable joints with the filter medium.

*Amendments to the paragraph beginning at page 6, line 5:*

~~According to a second aspect~~ In some embodiments of the invention, ~~there is provided~~ a filter assembly ~~comprising~~ may comprise a housing having an inlet and an outlet and a filter element that is integrity testable by the Diffusive Forward Flow Test or the Water Bubble Point Test, that is held in the housing and that comprises a filter medium having a central

passage extending between first and second ends of the filter medium, the housing being formed from a plastics material that is steam sterilizable.

*Amendments to the paragraph beginning at page 6, line 19:*

~~According to a third aspect~~In some embodiments of the invention, there is provided a valve for a filter assembly comprising ~~may comprise~~ an annular sleeve surrounding a passage of generally circular cross-section, movement of said sleeve in one sense opening said valve and movement of said sleeve in a sense opposite said one sense closing said valve.

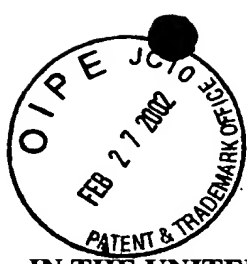
*Amendments to the paragraph beginning at page 7, line 1:*

~~According to a fourth aspect~~In some embodiments of the invention there is provided a valve comprising that may comprise a part defining a cylindrical passage and a valve member movable between a first position in which the member sits in and seals against the circumference of the passage to close the valve and a second position in which the member is located out of the passage to open the valve.

*Amendments to existing claims:*

1. (Twice Amended) A filter assembly comprising
  - a plastics housing providing an inlet port and an outlet port, the material of the housing being such that the assembly can be sterilized by subjecting the interior of the housing to steam under pressure while the exterior of the housing is at atmospheric pressure without damaging the housing,
  - a filter element held in the housing and comprising
    - a filter medium of water wettable material having a central passage extending between first and second ends of the filter medium,
    - the first end of the filter medium being embedded in a first end cap of a plastics material at a first joint to close said passage and the second end of the filter medium being embedded in a second end cap of a plastics material at a second joint, wherein the characteristics of the filter medium at the joints are not materially changed,
    - said second end cap providing a fluid connection between said passage and one of said ports,
    - the first and second end caps forming respective water-wettable joints with the filter medium.





**PATENT**  
Attorney Docket No. 440191/PALL

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

GUTMAN et al.

Application No. 09/462,765

Art Unit: 1723

Examiner: M. Savage

Filed: June 2, 2000

For: FILTER ASSEMBLY

**PENDING CLAIMS AFTER AMENDMENTS  
MADE IN RESPONSE TO OFFICE ACTION DATED OCTOBER 30, 2001**

1. A filter assembly comprising  
a plastics housing providing an inlet port and an outlet port, the material of the housing being such that the assembly can be sterilized by subjecting the interior of the housing to steam under pressure while the exterior of the housing is at atmospheric pressure without damaging the housing,  
a filter element held in the housing and comprising  
a filter medium of water wettable material having a central passage extending between first and second ends of the filter medium,  
the first end of the filter medium being embedded in a first end cap of a plastics material at a first joint to close said passage and the second end of the filter medium being embedded in a second end cap of a plastics material at a second joint, wherein the characteristics of the filter medium at the joints are not materially changed,  
said second end cap providing a fluid connection between said passage and one of said ports,  
the first and second end caps forming respective water-wettable joints with the filter medium.

2. A filter assembly according to claim 1, wherein said embedding involves heating the end caps to soften the end caps and inserting each one of said first and second ends into the associated end cap while the associated end cap is softened.

3. A filter assembly according to claim 2, wherein said first and second end cap plastics material is such that the characteristics of the filter medium adjacent to the end caps are not altered by said embedding.

4. A filter assembly according to claim 1, wherein the filter medium is composed principally of PVDF which has been modified to make the medium water-wettable, and the first and second end caps are composed of polypropylene.

5. A filter assembly according to claim 1, wherein the filter medium is composed principally of polysulphone which has been modified to make the medium water-wettable, and the first and second end caps are composed of polypropylene.

6. A filter assembly according to claim 1, wherein the filter medium is a FLUORODYNE or SUPOR medium and the first and second end caps are composed of polypropylene.

7. A filter assembly according to claim 1, wherein the filter medium is composed of a nylon material and the first and second end caps are composed of a polyester or a nylon material.

8. A filter assembly according to claim 1 wherein the filter element is integrity testable by the Diffusive Forward Flow Test or by the Water Bubble Point Test.

9. A filter assembly according to claim 2, wherein the plastics material of the first and second end caps can be softened at a temperature which is sufficiently low such that the integrity of the filter medium is undamaged when the filter medium is inserted into the first and second end caps when the first and second end caps are at said temperature.

13. A filter assembly according to claim 1, wherein the housing resists exposure of the interior of the housing to steam at about 121°C and about 1 bar above atmospheric pressure while the exterior of the housing is exposed to atmospheric pressure.

14. A filter assembly according to claim 1, wherein plastics material of the housing is one of polysulphone, PEEK, PEK, polyphenyleneoxide, polyphenylenesulphide, polyethersulphone, polyalkoxysulphone or polyarylsulphone.

15. A filter assembly according to claim 1, wherein said filter medium is generally annular, the first end cap being generally disc-shaped and the second end cap being generally annular with a central aperture for connection to one of said ports of the housing.

16. A filter assembly according to claim 15, wherein the filter medium is pleated.

17. A filter assembly according to claim 15, wherein the second end cap includes a projection defining a fluid path, said projection being received in the associated port to provide fluid communication therebetween.

18. A filter assembly according to claim 17, wherein said housing includes first and second opposed end walls, said housing port in fluid communication with the second end cap being formed in said second end wall, the filter element extending from said second end wall towards said first end wall.

19. A filter assembly according to claim 18, wherein the housing has a side wall of generally circular cross-section extending between said first and second end walls.

20. A filter assembly according to claim 1, wherein the housing is formed by first and second housing parts connected together.

21. A filter assembly according to claim 19, wherein the housing is formed by first and second housing parts connected together and wherein the first housing part includes said first end wall and said side wall and the second housing part includes said second end wall.

22. A filter assembly according to claim 20, wherein the first housing part and the second housing part co-operate to clamp the filter element between said housing parts to hold the filter element in the housing.

23. A filter element according to claim 22, wherein the filter element includes first and second oppositely facing clamping surfaces, the first housing part bearing against the first clamping surface and the second housing part bearing against the second clamping surface.

24. A filter element according to claim 23, wherein said first and second clamping surfaces are formed on said second end cap.

25. A filter element according to claim 24, wherein the first clamping surface is formed on at least one flange projecting from said second end cap.

26. A filter assembly according to claim 18, wherein the housing is formed by first and second housing parts connected together, wherein the first housing part and the second housing part cooperated to clamp the filter element between said housing parts to hold the filter element in the housing, wherein the filter element includes first and second oppositely facing clamping surfaces, the first housing part bearing against the first clamping surface and the second housing part bearing against the second clamping surface, wherein said first and second clamping surfaces are formed on said second end cap, and wherein said second clamping surface is formed on a portion of said second end cap extending around said projection.

27. A filter assembly according to claim 25 wherein said first housing part has a peripheral edge remote from said first end wall, said peripheral edge bearing against said at least one flange to force the second clamping surface against a portion of the second end wall of the housing around the associated port.

28. A filter assembly according to claim 1, wherein the filter medium is annular and has a curved exterior surface surrounded by a cage.

29. A filter assembly according to claim 28 wherein the cage is formed from the same material as the end caps.

30. A filter assembly according to claim 1, wherein the housing is provided with at least one valve that is manually operable to open and close the valve, the valve when open providing a fluid flow path between the exterior and the interior of the housing.

31. A filter assembly according to claim 30, wherein the or each said valve is formed from materials that can be steam autoclaved.

32. A filter assembly according to claim 31, wherein the or each valve is such that the assembly can be sterilized by subjecting the interior of the housing to steam under

pressure while the exterior of the housing is at atmospheric pressure without damaging the valve.

33. A filter assembly according to claim 30, wherein the or each valve is resistant to exposure of the interior of the housing to steam at about 121°C and about 1 bar above atmospheric pressure while the exterior of the housing is exposed to atmospheric pressure.

34. A filter assembly according to claim 30, wherein the or each said valve is formed principally from one of polysulphone, PEEK, PEK, polyphenyleneoxide, polyphenylenesulphide, polyethersulphone, polyalkoxysulphone or polyarylsulphone.

35. A filter assembly according to claim 30, wherein the or each valve includes an annular sleeve surrounding a passage generally circular in cross-section, movement of said annular sleeve in one sense opening said valve and movement of the annular sleeve in a sense opposite said one sense closing said valve.

36. A filter assembly according to claim 35, wherein the or each passage contains a valve member, movement of the associated sleeve causing said valve member to move between a first position in which said valve member permits flow through said passage and a second position in which said valve member prevents flow through said passage.

37. A filter assembly according to claim 36, wherein the or each valve member moves axially relative to the associated passage between said first and second positions.

38. A filter assembly according to claim 37, wherein the sleeve and the valve member of the or each valve are connected together, the sleeve surrounding said associated passage and the valve member extending into an end of said passage, said valve member including a passage which is in fluid communication with the associated passage when the valve is open and which is not in fluid communication when the valve is closed.

39. A filter assembly according to claim 35, wherein, for the or each valve, a mechanism acts between the sleeve and the housing such that rotation of the sleeve results in axial movement of said valve member between said first and second positions.

40. A filter assembly according to claim 39, wherein the or each mechanism limits the extent of the axial movement of the associated valve member.

41. A filter assembly according to claim 39 wherein the or each mechanism comprises a pin and a cooperating slot.

42. A filter assembly according to claim 41 wherein the or each pin is carried on an exterior surface of the housing and the associated slot extends helically partially around the sleeve.

66. A filter assembly according to claim 1, wherein the housing resists exposure of the interior of the housing to steam at about 142°C and at about 2.83 bars above atmospheric pressure while the exterior of the housing is exposed to atmospheric pressure.

67. A filter assembly according to claim 30, wherein the or each valve is resistant to exposure of the interior of the housing to steam at about 142°C and about 2.83 bars above atmospheric pressure while the exterior of the housing is exposed to atmospheric pressure.